

**Review paper****Lifestyle interventions for improving health and health behaviours in women with type  
2 diabetes: A systematic review of the literature 2011-2017**

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**Highlights**

- Healthy lifestyle behaviours are among the most promising and cost-effective strategies for reducing complications and premature death among women living with diabetes, though sustained uptake of the recommended lifestyle modifications is limited.
- This paper draws together the empirical literature from 2011 to 2017 on the effects of various lifestyle interventions of differing duration on a number of objective and subjective health indicators in women with T2DM.

- There was significant heterogeneity in the interventions and also the study findings, although exercise interventions generally provided the most consistent benefit in terms of glycaemic control.
- To improve their efficacy, interventions should target multiple health behaviours and emphasize health literacy, self-efficacy, and problem-solving skills.

## **Abstract**

The development and maintenance of healthy lifestyle behaviours are among the most promising strategies for reducing complications and premature death among women living with type 2 diabetes mellitus (T2DM). However, despite the potential benefits of these interventions, they have had varying success and the sustained uptake of the recommended lifestyle modifications is limited. This paper reviews research on the impact of lifestyle interventions aimed at improving health and health behaviours in women with T2DM. In a systematic review of the literature, empirical literature from 2011 to 2017 is examined to explore the effects of various lifestyle interventions on a number of objective and subjective health indicators in women with T2DM. A total of 18 intervention studies in women aged between 21 and 75 years were included in this narrative review. Interventions included education/counselling, exercise, diet, or combined components of varying duration. The included studies used a variety of objective indicators, including glycaemic control, lipid profile and anthropometric indices, as well as a number of diabetes-specific and generic subjective scales (for example, the Diabetes Problem Solving Inventory and the Short Form 36). Significant heterogeneity was noted in the interventions and also the study findings, although exercise interventions tended to yield the most consistent benefit in relation to glycaemic control, while exercise/dietary interventions generally improved anthropometric indices. The findings from this review did not consistently suggest the greater value of any

one type of intervention. Future research should consider interventions that target multiple health behaviours and emphasize health literacy, self-efficacy, and problem-solving skills.

*Keywords:* Health behaviour, modifiable lifestyle factors, type 2 diabetes mellitus, midlife women, older women, interventions.

ACCEPTED MANUSCRIPT

## 1. Background

Type 2 diabetes mellitus (T2DM) results from the body's ineffective use of insulin [1] and while it is often associated with 'Western lifestyle' [2], the prevalence of T2DM is rising fastest in low- and middle-income countries [3]. Global estimates suggest that more than 422 million people are living with diabetes [3], with T2DM accounting for 90% of cases [4].

Diabetes also increases the risk of other comorbid conditions. For example, a recent systematic review of more than 100 prospective studies showed that people with diabetes had a 2-3 fold increased risk of vascular diseases like coronary heart disease and ischemic stroke [5]. Other common consequences of diabetes, particularly in those with poor glucose control, include peripheral arterial disease, neuropathy, diabetic retinopathy, and kidney failure [3].

Clearly, there is a significant burden to those living with diabetes, their families, and the wider community in relation to escalating healthcare costs, lost productivity, and adverse social and economic outcomes for families [6]. Moreover, a recent systematic review of studies on the health expenditure of people with diabetes suggested that in 2015 the economic burden of diabetes was \$1.3 trillion USD or 1.8% of the global gross domestic product (GDP) [7]. As a result of the increasing prevalence of type 2 diabetes, its strong links with other co-morbid conditions, and significant social and economic burden, diabetes is one of four priority noncommunicable diseases (NCDs) identified in the World Health Organization's (WHO) *Global action plan for the prevention and control of NCDs 2013-2020* report.

While T2DM results from the interaction between lifestyle behaviours, environmental risk factors, and genetic predisposition, management of obesity and sedentary lifestyle are likely to prevent or delay over half of new cases in high-risk individuals [8-12]. Indeed, there is strong evidence from large-scale randomised controlled trials [10, 13, 14] and systematic reviews [8, 9, 11] that T2DM can be prevented, or at least delayed, in high-risk individuals

through lifestyle modification. Further, a number of translational studies based on clinical efficacy trials have recently demonstrated the effectiveness and cost-effectiveness of community-based interventions delivered in ‘real-world’ settings [15-17]. However, a major challenge remains in delivering effective diabetes self-management programs across different population groups and particularly in groups with poor adherence to lifestyle recommendations [18-20].

There are a number of key factors when developing health promotion interventions, including consideration of effectiveness, reach and adoption; workforce, technical and organisational resources; cost; intervention delivery; contextual factors; and appropriate evaluation approaches [21, 22]. Many diabetes self-management programs are multifaceted and have yielded differing results across population groups. Moreover, inherent biological differences, social, cultural, economic, environmental and political determinants of health between men and women might have added to inconsistent study outcomes.

This paper attempts to address some of these issues by drawing together empirical literature from 2011-2017 on the effectiveness of modifiable lifestyle interventions in women with type 2 diabetes. More specifically, this paper reviews recent research on the types and duration of interventions and their effectiveness in improving health behaviour. It is hoped that this paper will provide clearer recommendations for diabetes self-management programs in an effort to reduce future morbidity and premature death associated with this growing public health issue.

## **2. Methods**

The aim of this paper is to review the recent empirical literature (2011-2017) of interventions for improving health behaviours/health indicators in women with type 2 diabetes.

### *2.1 Search strategy*

Searches of MEDLINE, CINAHL, and PsycINFO databases were conducted in August-September 2017 using a standardized protocol (see Figure 1 for further detail). The All Text (TX) method was used to identify published peer-reviewed intervention studies published between 2011-2017 in the English language: ‘older women’ OR ‘female’ OR ‘midlife’ AND ‘T2DM’ OR ‘adult onset diabetes’ OR ‘diabet\*’ AND ‘exercise’ OR ‘physical activity’ OR ‘diet’ OR ‘smoking’ OR ‘alcohol’ OR ‘sleep’ OR ‘lifestyle modification’ OR ‘behaviour change’ OR ‘behavioural intervention’ OR ‘health education’ OR ‘health promotion’ AND ‘intervention’ OR ‘trial’ OR ‘RCT’ AND ‘mental health’ OR ‘physical health’ OR ‘functional ability\*’ OR ‘insulin resist\*’ OR ‘glucose levels’ OR ‘glycaemic control’ OR ‘weight loss’ OR ‘quality of life’ OR ‘self-management’ OR ‘behaviour change’ OR ‘health status’. In addition to searching academic databases, searches of trial registers (U.S. National Institutes of Health register, the EU Clinical Trials Register website, and the Australian New Zealand Clinical Trials Registry) were searched using the strategies outlined previously.

All citations identified in the searches were imported into the *Covidence* software, an online screening and extraction tool for the development of systematic reviews[23]. Once citations were entered, duplicate publications were removed and titles and abstracts were screened by two independent reviewers for relevance to the review question. Following this process, full copies of studies were retrieved and further assessed for eligibility. Articles were excluded if: they were not a primary intervention study (i.e., observational design, meta-analysis, review, study protocol, or letter), participants or variables of interest did not meet the inclusion criteria (research involving women with gestational diabetes, prevention studies and dietary/medical supplements), secondary publications of already included studies, or if papers did not disaggregate by gender.

## 2.2 Study selection criteria

This review considered studies published in English that included midlife and older women with type 2 diabetes where the intervention was related to lifestyle/health behaviour modification. The primary outcomes considered in this review were glycaemic control, diabetes self-management, health indicators, or compliance with positive health behaviours, or a combination of these variables.

This review considered both experimental and epidemiological study designs including randomized controlled trials, prospective and retrospective cohort studies, and cross-sectional studies. This review also considered systematic reviews and meta-analyses; however these studies were utilised only for background information and further identification of studies that met the inclusion criteria. Exclusion criteria were as follows: (1) qualitative research; (2) studies that did not include a control or comparison group; (3) duplicate publications or sub-studies of included research; (4) studies where full text or completed data were not able to be accessed, and; (5) studies that did not disaggregate by gender or variables of interest.

### *2.3 Methods for data extraction and assessing data quality*

Data were abstracted by two investigators from academic databases and trial registers using a standardized form. Screening of the extracted data included reviewing titles and abstracts based on study design, year of publication, population (age range and percentage of women), and definition of variables of interest. Where necessary, screening was performed by a third reviewer and consensus achieved by discussion.

### *2.4 Assessment of individual studies*

All included studies were assessed for potential bias associated with the mode, frequency and types of measurement; within-group and between-group similarities and differences; attrition; and adjustment for potential confounding variables.

The risk of bias in interventional studies was additionally assessed according to the Cochrane Handbook [24] and the *Covidence* standardized quality assessment form [23]: sequence generation; allocation concealment; blinding of participants and study personnel before and during the trial (in this instance it was not pragmatic for participants to be blinded to the intervention); blinding of the outcome assessor to participants group allocation; completeness of reported outcome data; whether selective outcome reported had occurred, and finally; other sources of bias that might have impacted study quality. Each of these criteria was rated in relation to the risk of bias, i.e., 'Low risk', 'High risk' or 'Unclear'.

### 3. Results

#### 3.1 Literature search

Data were abstracted into the *Covidence* software by two investigators, and verified through initial data abstractions. C.S. conducted the initial search ( $n = 403$ ), screened titles and abstracts of identified articles, and undertook the first iteration of excluding studies based on study design, year of publication, population (age range and percentage of women), definition of variables of interest, and duplication. N.M. searched grey literature ( $n = 5$ ) and undertook the first iteration of excluding studies based on the population, study design and objectives, data constructs and their measurement, whether trials had been completed and full data were available, and duplication.

In total, 403 full text articles were retrieved and reviewed by J.P. and C.S. to determine eligibility for inclusion (see previous section) in the review. Both reviewers agreed that an additional 91 papers should be excluded as they were not primary research studies (i.e., protocol papers;  $n = 6$ ), unable to retrieve the full-text record ( $n = 8$ ), they did not meet the inclusion criteria (e.g., the population included men or women but did not isolate results for women, the intervention was not lifestyle related, or was not designed for women with

T2DM;  $n = 67$ ), and 14 secondary papers of already included papers. Disagreement about the eligibility of one extracted study was resolved by a third reviewer (N.M) who excluded the record. In all, 18 studies met the inclusion criteria and were included in the narrative review [25-42].

Insert Figure 1 about here

### 3.2 Study characteristics

Table 1 outlines the characteristics of the sample, exposure variables or interventions, outcomes and results.

Insert table 1 about here

#### 3.3.1 Randomized Controlled Trials (RCTs)

Of the 14 RCTs included in this review, five originated from the United States of America (USA) [29, 34-36, 39], two originated from Europe (one from Italy[37] and one from Turkey[42]), six originated from Iran [26, 27, 30-33] and the remaining three RCTs originated from Asia (one from India [38], Japan [28], and Thailand[41]). The trial conducted in India was a three armed RCT and the one conducted in Japan was a Crossover RCT. The majority of these studies recruited participants through hospital or medical clinics. Lutes used additional methods of recruitment including advertising and flyers (5) and Schneider used mailings, newspaper advertising and online advertising to recruit participants. Four studies did not provide sufficient information about the recruitment strategies [33, 34, 36, 37].

While all studies included older people, five also specifically included younger people under 21 years of age [29, 30, 33, 36, 42] and one included postpartum women [41]. There were differences in age ranges between all studies.

Eligibility criteria for most studies included generally good health, and able to ambulate independently. Additional inclusion criteria were noted for several studies, for example, uncomplicated diabetes and no co-morbidities. In contrast, Schneider recruited participants with a major depressive disorder [36]. One study only recruited postmenopausal women [28]. Participants were generally excluded if they had serious medical conditions or cognitive impairment that may have either limited adherence to physical activity, or in which case physical activity may have been contraindicated. However, one study did not state any inclusion criteria [32].

### *3.3.2 Non-RCT Designs*

Two of the included studies used pre-test post-test designs [25, 40]. One American study recruited participants through a large health system and randomised them into one of two intervention groups [25]. This recruitment strategy yielded a small sample of 29 older women with a mean age of 53 years with a history of diabetes and suboptimal glycaemic control. The remaining study did not use a control group as it formed part of a larger trial of a behavioural weight control program [40]. African-American women were eligible if they were generally healthy and could walk for exercise. In total 84 women participated in the study with a mean age of 49 years.

## *3.4 Intervention types*

### *3.4.1 Exercise intervention*

The exercise intervention was also administered differently across the included studies. For example, AminiLari [26] examined the impact of 12 weeks of aerobic, resistance and combined exercises, Dodgostar [27] compared a supervised group based exercise therapy

versus home-based exercise therapy program, and three studies implemented aerobic exercise three times weekly [32, 33, 35]. Several studies compared less vigorous exercise interventions including Sreedevi [38] who trialled a yoga intervention, Youngwanichsetha [41] who trialled five weekly tai chi qigong sessions over 12 weeks, and Yucel [42] examined the impact of regular pilates for 12 weeks. Finally, Sentinelli [37] investigated the impact of increasing volumes of supervised Nordic walking for 12 weeks on body composition.

#### *3.4.2 Diet intervention*

Again, there was heterogeneity in intervention types with a range of diets being trialled. Specifically, Kondo [28] used a fish based diet, and Madjd [30] compared substituting diet beverages with water with continuing to consume diet beverages, and two others combined hypocaloric diets with physical activity in their interventions [34, 35]. Pownall [34] restricted calorie intake to either 1200-1500 kcal/day or 1500-1800 kcal/day depending on participants initial weight and used diet in conjunction with 175 minutes of aerobic activity per week while Ryan [35] combined a very low calorie diet (250-350 kcal/day) with three aerobic exercise sessions per week.

#### *3.4.3 Education intervention*

Consistent with previous studies, the content and delivery of educational interventions varied significantly. Allen [25] trialled individualized continuous glucose monitoring counselling in conjunction with either general diabetes education alone or problem-solving skills. Mahdizadeh [31] used education pamphlets, fact notes and slides along with physical activity training DVDs along with group-based theory (4) and practical sessions (3) in a month period while Toobart [39] used peer-led group meetings to build skills including diet and physical activity.

Insert Table 2 about here

### 3.5 Outcome measures

A large range of objective outcome measures were reported across studies including body mass index (BMI), waist circumference (WC), fat mass (FM), blood pressure (BP), lipid profile (including high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, total cholesterol, and triglycerides), glycated haemoglobin (HbA1c), and fasting insulin and blood glucose.

A wide variety of subjective measures were used across the 18 studies. These included diabetes specific constructs including self-care [43, 44], empowerment (Diabetes Empowerment Scale [45]), distress (Diabetes Distress Scale [46]), problem solving (Diabetes problem-solving Inventory [47]), medication adherence (Morisky medication Adherence [48]), confidence to overcome self-care challenges (Confidence in Overcoming Challenges to Self-Care [49]), and diabetes complications (Michigan Neuropathy Screening Instrument [50]).

Other authors used instruments with an emphasis on chronic disease self-management (Brief Chronic Illness Resources Survey [51], Treatment Satisfaction Questionnaire [52]) while others used generic subjective measures to assess psychosocial health indicators (for example, Short Form 36 [53], Center for Epidemiologic Studies Depression Scale [54], Beck Depression Inventory [55], Behavioral Activation for Depression Scale [56], HRSD Hamilton Rating Scale for Depression [57]).

Finally, as many interventions included dietary or exercise components or activities to increase self-efficacy, several subjective measures assessed changes in lifestyle behaviour or self-efficacy. Again, there numerous instruments used, many of which measured related, but sometimes different constructs (see Table 3 for further detail).

Insert Table 3 about here

### *3.6 Quality assessment*

Findings of the quality assessment are detailed in Table 4. A proportion of the trials examined in this review had an unclear risk of sequence generation bias. For example, 9 studies did not provide clear or sufficient detail about the process of sequence generation [26-29, 33, 35, 37, 39, 42]. Only six trials provided detail about the concealment of allocation, two using sequentially numbered, opaque, sealed envelopes [25, 41], one used coded cards [32] and three were stratified using randomisation software and blocked with random block sizes [30, 34, 36]. The concealment was unclear for the remainder of the studies upon reading the articles. For example, one study stated that group allocation occurred when participants attended an in-person screening visit at their local rural community facility or church but the authors do not outline when or by whom [29].

Only five studies provided details of blinding of outcome assessors [34, 36, 38, 39, 41]. Around half of the studies either failed to blind study personnel and/or the outcomes, or provided insufficient information to determine whether blinding had occurred [25, 27, 28, 31, 32, 35, 37, 40, 42], while two studies had a high risk of bias of blinding participants/personnel for outcomes [26, 33]. For example, AminiLari [26] did not provide any details on how the participants or personnel were blinded for the study. Upon reading the articles, outcome data for three studies was unclear [33, 37, 39] and the outcomes reported by White [40] had a high risk of bias. White [40] only reported on weight change, weight loss goals and expected weight loss satisfaction. With the exception of this study [40] all studies had a low risk of bias of selective outcome reporting. Overall, eight studies were found to have a low risk of bias [25, 30, 31, 34, 36, 38, 39, 41]. A proportion of the trials examined in this review had an unclear risk of bias.

Insert table 4 about here

### 3.7 Study findings

Table 5 details the findings for the objective measures by intervention types. Because of the small sample size in many of the studies the ability to reach statistical significance was reduced and thus a significant effect was determined using several metrics: (1) where authors reported statistical significance ( $p < .05$ ); (2) where authors reported a moderate effect (i.e. Cohen's  $d \geq 0.5$ ), or; (3) where a standardized mean difference (SMD)  $\geq 0.5$  was evident on visual inspection using baseline standard deviation as a reference point.

BMI was significantly reduced in several of the studies. For example, AminLari [26], Dodgostar[27], Madjd [30], Sentinelli [37], Sreevdi [38] and Ryan [35] all reported a significant post-intervention effect on BMI. Similarly, WC was significantly reduced in five studies [27, 30, 32, 35, 38], three of which were exercise based interventions [27, 32, 38], one of which combined diet and exercise [35], and the final included a hypocaloric diet and restricted diet beverages or water consumption [30].

Several studies reported a significant post-intervention effect on HbA1c levels. For example, Toobert [39] who used education and counselling reported improvements at six month follow up and they were maintained at 12 month follow up. Dadgostar [27], Sentinelli [37], Youngwanichsetha [41], and Yucel [42] all implemented exercise interventions and reported improvements on HbA1c levels. Fasting blood glucose levels also had significant improvements in the majority of exercise interventions [27, 37, 41, 42] and Ryan's combined diet and exercise intervention [35].

Insert table 5 about here

Differences in reporting of some subjective scales hampered comparison across studies even when comparable instruments were used. For example, Nahdizadeh and Schneider both used the Social Support for Exercise Survey or SSES [58], though Mahdizadeh only reported on whether “family or friend changed their schedule so we could exercise together” [31] and Schneider provided results of three sub-scales “family participation”, “friend participation”, and “family/reward/punishment”. Similarly, while two authors [27, 42] assessed HRQoL using the SF-36 [53], Dadgostar presented the eight subscales and Yucal reported the mental health and physical health component summary scores.

Diabetes problem solving and self-care (DPSI [47]) seemed to be improved through a psychosocial intervention (i.e., general and T2DM health education, problem-solving skills) though the benefit of this intervention type was not universal; Allen [25] and Toobert [39] demonstrated a positive effect, while Sreedevi study [38] did not. Moreover, while Allen [25] and Toobert [39] demonstrated a positive intervention effect in relation the DPSI and also increases in moderate physical activity, this did not result in corresponding improvements in Self-efficacy for Exercise Behavior Scale [59].

#### **4. Discussion**

Changes in lifestyle behaviours in recent years have corresponded with increases in many lifestyle diseases. Indeed, it is estimated that around 380 million people are living with T2DM [3], which not only causes morbidity and mortality in and of itself but it also increases the risk of other chronic disease like coronary heart disease and ischemic stroke [5]. Consequently, there is growing impetus to prevent and manage chronic disease early and thus potentially avoid costly and potentially debilitating health sequelae in the

future. Research has shown that good glucose control has the potential to significantly improve short term outcome (diabetes symptomology and quality of life [60]), decrease complications and health care expenditure associated with T2DM [60, 61], and also reduce cardiovascular events [62].

In terms of glycaemic control, exercise interventions generally yielded the greatest impact on fasting insulin, blood glucose and glycated haemoglobin. Notably however, while the intervention yielded a positive effect post-intervention, in some instances this effect was not sustained over time (for example, Mean FBG ( $\text{mg}\cdot\text{dL}^{-1}$ ) = 136, SD = 28 at baseline ( $T_0$ ), 121, SD = 19 post-intervention ( $T_1$ ), the effect was not sustained 6 months post-intervention 131, SD = 26 ( $T_2$ ). Similar trends were seen for HbA1c [37]). One possible explanation is related to knowledge deficits among participants. A recent study among patients with T2DM and their treating clinicians showed little understanding of the locus of control and few had adequate understanding of the correlations between lifestyle and progression of the disease [63]. From this perspective, interventions with diabetes education and self-efficacy components might provide a sustained effect that lasts beyond the duration of the intervention.

Anthropometric measures were largely responsive interventions that included dietary and/or exercise modifications. For example, Madjd [30] showed reductions in BMI in both the H<sub>2</sub>O and diet beverage groups over time ( $T_0$   $M_{\text{BMI}} = 32.9$ , SD = 1.7,  $T_1$   $M_{\text{BMI}} = 31.3$ , SD = 2.0 and  $T_0$   $M_{\text{BMI}} = 33.2$ , SD = 2.2,  $T_1$   $M_{\text{BMI}} = 31.8$ , SD = 2.1 respectively), Ryan [35] showed a significant reduction in BMI in both the diet only and diet plus exercise groups and Youngwanichsetha [41] showed a non-significant modest reduction in body mass ( $T_0$   $M_{\text{BMI}} = 26.8$ , SD=3.2;  $T_1$   $M_{\text{BMI}} = 25.5$ , SD= 3.6). Thus while only small changes in BMI were detected, research suggests that decreasing BMI by one point alone (i.e., three kilograms)

could result in more than 25 fewer cases of chronic disease per 1,000 persons [64] and an estimated 14% reduction in disease burden over the next decade [65].

Overall, the results of the included studies demonstrated varying success on their respective health indicators. This is possibly due to the often singular approach used in many of the interventions and their failure to address the broader and correlated nature of many unhealthy lifestyle behaviours [66]. For example, while weight gain can be largely attributed to changes in lifestyle behaviours (i.e., eating habits, physical inactivity and sleeping patterns), broader economic, political, cultural, technological changes associated with globalisation also play a pivotal role in the increasing obesity prevalence [67]. Moreover, recent studies have suggested that among low income women, obesity is often also linked with sedentary behavior and poor dietary behaviors[68]. However, despite the concurrence of many risk factors, few interventions have used a whole-of-lifestyle approach. Obesity interventions usually fall into lifestyle (diet and/or exercise), medical (pharmacological) or surgical interventions. A recent Cochrane review suggested that dietary interventions generally resulted in short term weight losses but there was inconclusive evidence about long-term sustainability [69].

Taken together, the results of the included studies and supporting empirical literature suggests the need for multiple health behaviour change (MHBC) interventions that emphasize health literacy, self-efficacy, and problem solving skills. In so doing, this is likely to address two of the main limitations of many previous interventions, i.e., building personal resources to enhance self-management capacity and the need to consider health within the broader ecological context.

Several study limitations should be noted. First, over half of the included studies were derived from pilot work or interventions conducted in small samples (five reported  $n \leq 30$ , one reported  $n = 45$ ) which might have influenced ability to detect a positive intervention

effect. Previous studies have highlighted the difficulties in recruiting this population. For example, a trial from Monash University in Australia was abandoned due to recruitment failure (four participants were recruited in five months) [70].

Another limitation related to study quality. Some of the included studies lacked sufficient methodological detail to determine risk of bias. Moreover, the trials had numerous methodological differences (interventions, instruments, design, analysis, etc.), and were conducted over varying timeframes. Even where similar interventions were conducted, significant differences in the delivery mode and timing of interventions were noted and this prevented meta-analyses. Despite these limitations however, this review explored recent interventions in improving health and health behaviours in women with T2DM. Given the heterogeneity of the included studies it is not surprising the variability of effect. However, despite the lack of consistency in study finding it is likely that lifestyle interventions, particularly those embedded within a broader lifestyle program (i.e., targeting multiple health behaviours) have a positive impact on both subjective and objective indicators of health.

### **Contributors**

Charlotte Seib conceived and designed the review, conducted the literature search and review, and analysed and interpreted the data.

Joy Parkinson conceived and designed the review, conducted the literature search and review, and analysed and interpreted the data.

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Debra Anderson conceived and designed the review.

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### **Conflict of interest**

The authors declare that they have no conflict of interest.

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## Figures

Figure 1 *PRISMA flowchart for study selection [71]*

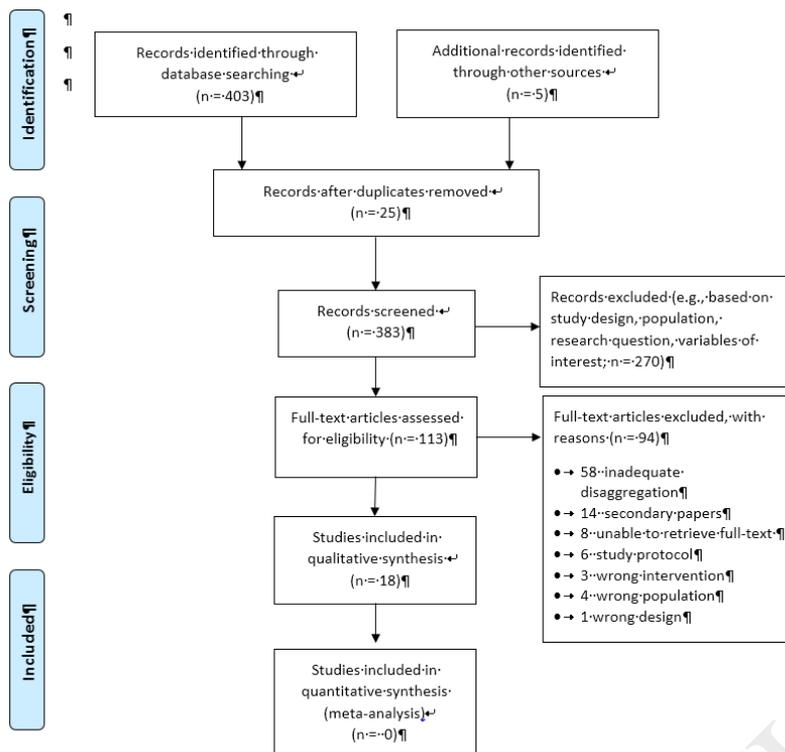


Table 1

Summary of the interventions to improve health behaviours in women with T2DM (2011-2017)

Authors	Country	Purpose	Design	Duration of intervention	n	Inclusion criteria and sample characteristics	Intervention type	Outcomes	Result
Allen [25]	USA	Evaluate feasibility, acceptability, and preliminary efficacy of intervention	pre-test–post-test design	12 weeks	29	30-65 years, exercising $\leq$ 2 week, able to walk 0.25 miles/ 10 min, HbA1c $>$ 7.0%, not using insulin, read and speak English  M <sub>age</sub> = 52 $\pm$ 6.5-8, M <sub>T2DM</sub> = 7 years $\pm$ 4.6-6, 67% Caucasian, 13% Latina, 20% African American	CGM counselling $\pm$ 1. counselling for problem-solving skills 2. diabetes education	PA amount/intensity, diet, problem-solving skills, self-efficacy for PA, depression, BP, BMI, HbA1c	CGM+ problem solving group had $\uparrow$ problem-solving skills (p $<$ .05)  Dietary adherence (n/s), moderate activity minutes (n/s), weight loss (n/s), and higher intervention satisfaction (n/s)
AminiLari [26]	Iran	Evaluate impact of an exercise intervention on omentin-1 level, glucose and insulin	RCT	12 weeks	52	45-60 years, T2DM for $\geq$ 2 years, no other co-morbidities  Overweight/obese middle-aged ♀	Three exercise groups: 1. aerobic (AE) 2. resistance (RE) 3. combined (CE)	BMI, body composition (% body fat), omentin-1, fasting insulin, FGG, HOMA-IR	RE and CE: $\downarrow$ BMI and weight over time (within group n/s)  CE: $\uparrow$ omentin-1 and $\downarrow$ body fat over time (p $<$ .05) AE and RE: $\downarrow$ HOMA-IR BSL $\downarrow$ in all groups
Dodgostar [27]	Iran	Compare effect of supervised group vs. home-based exercise therapy on HRQoL.	RCT	12 weeks	102	$>$ 30 years, uncomplicated T2DM 2+ years, not using insulin, HbA1c $\leq$ 10, read and speak Farsi.	Supervised group exercise-therapy program (SET) vs. Home-based exercise-therapy	FBG, TC, HDL-c, TG, LDL-c, HbA1c, BMI, HRQoL	SET: $\uparrow$ mean role-physical, general health (within and between

		anthropometrics, glucose and lipids				no impairments that prevent compliance  M <sub>age</sub> = 50 ± 5-6, Median duration of T2DM: SET 7 years (1 month-25 years), HET 4 years (1 month-20 years)	program (HET)		p<.05), ↓BMI, weight, TG, HbA1c, mean body fat mass  ↓WC in both groups, magnitude generally greater in SET group
Kondo [28]	Japan	Compare the effects of a fish-based diet on endothelial function	RCT – crossover	8 weeks (cross-over at 4 weeks)	23	Not taking fish oil supplements, insulin and no allergy to fish, good glycaemic control, non-smokers, moderate alcohol  Post-menopausal ♀, M <sub>age</sub> = 70 ± 7, M <sub>BMI</sub> = 22 ± 3	Fish-based diet (n-3 PUFAs ≥ 3.0 g/day)	Basal forearm blood flow (FBF), reactive hyperemia (RH), peak FBF response, duration RH, total RH flow, weight, body comp., FBG, TC, HDL-c, TG, LDL-c, HbA1c, HOMA-IR	A fish-based diet improved Peak FBF by 63.7%, duration RH by 27.9% and FDR by 70.7%, compared to the controls.  Serum n-3 PUFA levels increased after fish-based diet and decreased after the control diet (1.49 vs. 0.97 vs. 1.19 mmol/l, p < 0.01).
Lutes [29]	USA	Examine the impact of a small changes lifestyle intervention delivered by community health workers (CHW)	RCT	12 months	200	Rural African American women aged 19-75, HbA1c ≥ 7%, able to read and write in English  M <sub>age</sub> = 53 ± 10, 47% high school education or less, 79% <\$30,000	Intervention comprised 16-week EMPOWER treatment manual, scales, a glucose monitor, and pedometer, reviews/monitoring with CHW	HbA1c, weight, BP, Diabetes empowerment, self-efficacy and self-care	No differences in HbA1c (-0.29 ± 1.84 vs + 0.005 ± 1.61; p = .7) or BP (-1.01 ± 20 / +0.6 ± 13 vs + 0.2 ± 25/-2.8 ± 1.52; p = .1)

						annual income			↓ weight in INT groups (-1.3 ± 6.2 kg vs. -.4 ± 4.6 kg, p = 0.04)
Madjd[30]	Iran	Compare the effect of replacing diet beverages (DBs) with water on weight loss	RCT	24 weeks	81	Aged 18-50 years; BMI, 27-35 kg/m <sup>2</sup> ; 6.5 < HbA1c < 7.2, only using metformin; self-reported habitual DBs and willing to introduce a dietary change to lose weight  M <sub>age</sub> = 24-35 ± 7, over 75% married	Hypo-energetic diet +: 1. H <sub>2</sub> O only post-lunch (main meal) 2. 1 glass of DB post-lunch only p/d	BMI, WC, FPG, fasting insulin, HOMA-IR, HbA1c, TC, HDL-c, TG, LDL-c	H <sub>2</sub> O group had greater ↓ in weight, (p < .01), BMI (p < .01), FPG (p < .01), fasting insulin (p = .01), HOMA-IR (p < .01). Time × group interaction n/s for WC, lipids and HbA1c
Mahdizadeh [31]	Iran	Effectiveness of education based on social cognitive theory on promoting physical activity	RCT	8 weeks	82	Aged 35-60 years, uncomplicated diabetes, able to read and write Farsi, undertaking exercise  M <sub>age</sub> = 48 ± 6, M <sub>T2DM</sub> = 65.04 months ± 53.52	Educational pamphlets, fact notes, slides, physical activity training DVDs; 7 sessions (4 theory and 3 practical sessions) in a month (each session ≈ 60 min),	Task self-efficacy, barrier efficacy, social support and exercise, outcome expectations, walkability, IPAQ	INT group: ↓ light physical activity and sedentary behavior from 56% to 15%. ↑ mean minute's physical activity (p = .04) and difference in social-cognitive theory constructs (p .05).
Motahari [32]	Iran	Compare the effect of aerobic exercise on insulin resistance	RCT	8 weeks	62	Inclusion criteria not stated but participants matched by age and BMI  M <sub>age</sub> = 49 ± 1, almost half had primary education, all worked at home	50 minute of supervised moderate-intense aerobic exercise 3 x weekly for 8 weeks	BMI, WC, HC, FBG, fasting insulin, HOMA-IR	↓ weight (p = .01), WC (p < .01), HC (p < .01), BMI (p = .01), fasting insulin (p < .01), and HOMA-IR

									(p<.01) in both groups over time. Time x group interaction significant for WC, HC, FBS, fasting insulin, HOMA-IR
Nadi [33]	Iran	Examine the effects of 12 weeks combined training with Vitamin D supplement on improvement of sensory motor neuropathy	RCT	12 weeks	90	Diabetic neuropathy for > 5 years, no other comorbidities, aged 20-55 years  M <sub>age</sub> = 45-46 ± 7-8	Vitamin D supplementation ± 12 week aerobic exercise program (3 x weekly)	Self-reported pain, numbness, tingling, weakness, and disability in lower limbs. reflection hammer measured reflexes and touch	INT group: ↓numbness (p<.01), pain (p<.01), tingling (p<.01), lower limb weakness (p<.01) ↑ sense of touch (p<.01), vibration perception (p<.01)
Pownall [34]	USA	Examine impact of lifestyle intervention on body composition in overweight / obese adults	RCT	Delivered over 4 years [72]	1019, 60% ♀	Aged 45-75, BMI ≥25 kg/m <sup>2</sup> (or ≥27 kg/m <sup>2</sup> if receiving insulin)  M <sub>age</sub> = 59 ± 7, 13% African American, 8% Hispanic, 74% Caucasian	Hypocaloric diet + 175 minutes physical activity per week	Weight, body composition (LM, FM)	Between baseline and year 8, ↑ weight loss in intervention vs. comparison (4.0 ± 0.4 vs. 2.3 ± 0.4 kg); comparison group weight loss mostly lean mass
Ryan [35]	USA	Examine whether hypocaloric diet alone or with exercise training is effective in improving body composition, fitness, glucose	RCT	6 months	25	Overweight/obese, aged of 44-68 years, BMI 29-40 kg/m <sup>2</sup> , history of GDM  M <sub>age</sub> = 52-54 ± 2	Hypocaloric diet (WL) ± aerobic exercise (AEX) 3 x weekly	VO <sub>2max</sub> , BP, BMI, WC, HC, body composition, TC, TG, HDL-c, TG, LDL-c, oral glucose tolerance, exogenous insulin	Weight and FM ↓ both groups (p <.01). Visceral and subcutaneous abdominal fat ↓27 and 10% after WL (p < .01) and 14

		utilization and CVD risk factors							and 11% after AEX + WL ( $p < .05$ ). $VO_{2max}$ ↑16% after AEX + WL ( $p < .01$ ) and
Schneider [36]	USA	Feasibility of behavioural activation (BA) and structured exercise program on depression	RCT	6 months	29	Aged 21–65 years, HbA1c level of 7–10%, major depressive disorder as defined DSM-IV, BMI 18.5–45 kg/m <sup>2</sup> , inactive.  $M_{age} = 53.4 \pm 7.1$ , mostly Caucasian,	90 mins structured group exercise class with BA content	HbA1c, depressive symptoms, PA, BMI, exercise self-efficacy, social support, behavioural activation for depression	No condition differences were observed for glycemic control, depressive symptoms, and PA. Compared to controls, exercise group ↑ exercise enjoyment and no increase in avoidance behavior over time.
Sentinelli [37]	Italy	Evaluate the effects of Nordic Walking structured training on anthropometric, metabolic and bioelectrical variables	RCT	6 months (12 week INT)	20	Aged 40–70 years, inactive, T2DM $\geq 1$ year, good glycaemic control, HbA1c 6% - 10%, BMI $> 25 \text{ kg} \cdot \text{m}^{-2}$	Supervised Nordic Walking for 12 weeks with increasing volumes of training	HbA1c, HDL-c, LDL-c, TG, AST, ALT, BMI, body composition, hand grip strength	INT group: ↓ HbA1c (-0.7%), BMI (-0.8 kg·m <sup>-2</sup> ) and body weight (-2.4 kg), and ↑ HDL-c (+5.8 mg·dL <sup>-1</sup> ). Also strength ↑ for Handgrip Test (+4.3 kg)
Sreedevi [38]	India	Effectiveness of two INT; yoga and peer support on glycaemic outcomes	3-armed RCT	3 months	124	Aged 30–65 years, T2DM $< 8$ years, HbA1c 7-10%.  $M_{age} = 52 \pm 7$ , $M_{T2DM} = 5 \pm 3$ years.	Yoga: 60 mins twice weekly  Peer support: Weekly group-based peer meetings covering self-	FBG, HbA1c, HRQoL	Yoga group: n/s ↓ FBG and HbA1c. ↓systolic BP and HC ( $p < .05$ ). Good adherence

							management and support		, 80% in the yoga group and 90% in the peer group
Toobert [39]	USA	Test cultural adaptation of MHBC INT ;Viva Bien!	RCT	12 months	280	Latinas, aged 30–75 years, T2DM for $\geq 6$ months, live independently, contactable by phone, able to read English or Spanish, no limitation that would prevent compliance.  $M_{age} = 57 \pm 10$ , many diagnosed with diabetes for almost 10 years	Usual care + ;Viva Bien! INT - group meetings for building skills r/t diet, PA, smoking cessation etc	Self-efficacy, self, social support, stress management, FFQ, IPAQ, HRQoL, HbA1c	INT group: ↓ fat intake, HbA1c, ↑ stress management practice, PA, and accessing social–environmental support) at 6 months, some improvements maintained at 12 months.
White [40]	USA	Examined weight loss goals and satisfaction with reasonable weight loss	Pre-post-trial (no control)	6 months	84	African American, BMI= 27–50kg.m <sup>-2</sup> , able to undertake intervention, HbA1c < 12%  $M_{age} = 49 \pm 9$	24-session group behavioural obesity intervention	BMI, satisfaction with weight loss	Women weight loss goal was 31 pounds (14 kg or 14% of body weight) over the 6-months. Would be fairly satisfied (Likert scale extremely satisfied - extremely dissatisfied) with a 15–20 pounds weight loss. On average the sample lost 3.0 kg (3% of initial weight).
Youngwanichsathaporn [41]	Thailand	Examine the effect of tai chi	RCT	12 weeks	69	♀ 6-12 weeks postpartum	5 x weekly tai chi qigong	BMI, BP, FBG, HbA1c	INT group: ↓ FBG,

		qigong exercise on plasma glucose levels and health				with T2DM, FBG 110 and 150 mg/dl, HbA1c $\geq$ 6.5%, uncomplicated and not taking medication for diabetes	for 12 weeks at home, 3–6 months postpartum		HbA1c, BP at 12 weeks ( $p < .05$ ). FBG for INT and controls were $120. \pm 17.51$ mg/dl and $129.88 \pm 5.23$ mg/dl, respectively at 12 weeks.
Yucel [42]	Turkey	Examine effects of Pilates-based mat exercise on glycemic control, anxiety, depression, and HRQoL	RCT	12 weeks	45	Aged 18- 65 years, not doing regular physical exercise, uncomplicated, no conditions that would limit compliance	PBME 3 x weekly for 12 weeks	Pain, fatigue, HRQoL, HbA1c, FBG, postprandial blood glucose	Between group over time ↓ Pain, fatigue, Anxiety, depression, FBG, HbA1c, and ↑ HRQoL in INT group ( $p < .05$ ).

INT, intervention; PA, physical activity; BP, blood pressure; BMI, body mass index; HbA1c, glycated haemoglobin; CGM, continuous glucose monitoring; n/s, not significant; RCT, randomised controlled trial; HOMA-IR, homeostatic model assessment insulin resistance; WC, waist circumference; HC, hip circumference;  $VO_{2max}$ , maximum oxygen consumption; FBG, fasting blood glucose; TC, total cholesterol; HDL-c, high-density lipoprotein cholesterol; TC, total cholesterol; TG, triglyceride; LDL-c, Low-density lipoprotein cholesterol; HRQoL, health-related quality of life; PUFA, polyunsaturated fatty acid; p/d, per day; IPAQ SF, International Physical Activity Questionnaire (IPAQ) - Short Form; LM, lean mass; FM, fat mass; GDM, gestational diabetes mellitus; AST, aspartate aminotransferase; ALT, alanine aminotransferase; r/t, related to; MHBC, multiple health behaviour change

Table 2

*Summary of interventional activities for the included studies*

	CGM PA counselling	Cognitive restructuring	Diabetes education	Aerobic	Strength	Combined/ other exercise	Dietary modifications
Allen [25]	90-min individualized session about effects of PA on blood glucose	90-min session about barriers to PA, techniques for problem-solving	General education about foot care, eye care, taking blood sugar etc				
AminiLari [26]				3 x weekly: 20 min warm-up, 25 mins exercise to 50-55% max. HR, cool down	3 x weekly: warm-up, 3 sets of 8 reps weights to 50-55% rep max, cool down	3 x weekly: aerobic and strength increased by 5 mins and 5% intensity fortnightly	
Dadgostar [27]					3 x weekly - week 1-6; 1 p/w - week 7-12: warm-up + stretching, 2-3 sets of 10-15 reps resistance with Thera-band, cool down	30 min individual session to receive instructions and equipment	
Kondo [28]							3.0 g/day n-3 PUFA derived from fish, e.g., Pacific saury, salmon, sardines, etc
Lutes [29]		Small Changes-consistent goal setting, problem solving, cognitive reappraisal, coping with stress, mindfulness, etc	Self-monitoring, diabetes 101, health education				
Madjd [30]							Hypo-energetic diet and

							beverage substitution (H <sub>2</sub> O only vs. 1xDB p/d)
Mahdizadeh [31]		Based on SCT, includes self-regulation, self-efficiency strategies, social support to promote physical activity		7 sessions (4 theory and 3 practical sessions) in a month (each session ≈60 min)			
Motahari [32]				3 x weekly for 8 weeks warm-up, 30 mins walking at 60% HR <sub>max</sub> , cool down			
Nadi [33]						3 x weekly for 60 mins aerobic exercise 60–70% HR <sub>max</sub> and resistance training intensity (10 R.M.)	
Pownall [34]				175 minutes PA per week			Caloric intake of 1200–1500 or 1500–1800 kcal/day (depending on initial weight)
Ryan [35]				Stretching and warm-up, exercise ~50–60% HR <sub>max</sub> (↑ intensity to >60% VO <sub>2</sub> max for 45 min max HR), cool down			Restricted caloric intake (250–350 kcal/day)
Schneider [36]		BA - monitoring activity and mood, activity experiments, behavioural		2 x weekly for 16 weeks, 1 x weekly for 4 weeks, 1x			

		contract to promote exercise; and values and activities assessment		fortnightly for 4 weeks. 90-min sessions including warmup; exercise, cool down			
Sentinelli [37]				3 x weekly for 12 weeks 60-90 min sessions of supervised Nordic Walking with ↑ volume of training			
Sreedevi [38]			Weekly group-based 45–60 min sessions on self-management, diet, exercise, stress, foot care, social and emotional support, weekly follow-up phone calls, monthly review by research team			2 x weekly 60 min yoga including 25 min-Surya namaskara-12 steps, 5–7 min deep muscle relaxation, 15 min yoga postures, 15 min pranayama	
Toobert [39]		2.5-day retreat + weekly meetings for 6 months, then fortnightly for 6 months. Topics: Mediterranean diet, stress management, techniques, 30 min of daily PA, smoking cessation, problem-solving					
White [40]		24 x weekly group session over 6					

		months. Behavioural obesity intervention focusing on promoting Diet, PA, and support strategies					
Youngwanichsetha [41]						5 x weekly tai chi qigong exercise: warm-up (25 movements for 15 min), tai chi qigong after 1 x Lin Housheng style comprising 18 movements for 30 min, cooling down	
Yucel [42]			Half-day education session about diabetes and exercise			3 x weekly for 12 weeks, diaphragmatic breathing, warm-up, stretching; basic aerobic Pilates training for arms, legs, and body, cool-down. Increasing duration from 45 - 70 mins	

PA, physical activity; mins, minutes; p/d, per day; DB, diet beverage; SCT, Social Cognitive Theory; PUFA, Poly-Unsaturated Fatty Acid; g/day, grams per day; HR<sub>max</sub>, maximum heart rate based on age and gender; kcal/day, kilocalorie per day

Table 3

Summary of outcome measures of the included studies

	[2 5]	[2 6]	[2 7]	[2 8]	[2 9]	[3 0]	[3 1]	[3 2]	[3 3]	[3 4]	[3 5]	[3 6]	[3 7]	[3 8]	[3 9]	[4 0]	[4 1]	[4 2]
<b>General objective measures</b>																		
<i>Anthropometrics</i>																		
Weight/BMI	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
WC						✓		✓			✓			✓				
HC								✓			✓			✓				
Body composition		✓		✓						✓	✓		✓					
<i>Other physical measures</i>																		
BP	✓			✓	✓													✓
Endothelial function				✓														
Knee/ankle reflexes									✓									
Hand grip strength													✓					
VO <sub>2max</sub>											✓							
Indirect calorimetry											✓							
Electronic PA monitor	✓		✓		✓	✓						✓						
<i>General serology</i>																		
TC			✓	✓		✓					✓			✓				
HDL-c			✓	✓		✓					✓		✓					
LDL-c			✓	✓		✓					✓		✓					
TG			✓	✓		✓					✓		✓					
AST													✓					
ALT													✓					
<b>Diabetes-specific objective measures</b>																		
Oral glucose tolerance											✓							
Hyperinsulinemic-euglycemic clamps											✓							
HbA1c	✓		✓	✓	✓	✓		✓				✓	✓	✓	✓		✓	✓
omentin-1		✓																
Fasting insulin		✓		✓		✓		✓										
FBG		✓	✓	✓		✓		✓						✓			✓	✓
HOMA-IR		✓		✓		✓		✓						✓				
<b>Subjective diabetes experience</b>																		
Summary of the Diabetes Self-Care [43, 44]	✓				✓													
DES [45]					✓													
DDS [46]					✓													
DPSI [47]	✓														✓			
Morisky Medication Adherence [48]					✓									✓				
Confidence in Overcoming Challenges to Self-Care [49]															✓			
Michigan Neuropathy Screening Instrument [50]									✓									
<b>Chronic disease focus</b>																		
Brief Chronic Illness Resources Survey [51]															✓			
Treatment Satisfaction Questionnaire [52]																		✓
<b>General psychosocial measures</b>																		
<i>HRQoL, anxiety and depressive symptoms</i>																		
SF-36 [53]			✓															✓
CES-D [54]	✓																	
Beck Depression Inventory [55]												✓						
BADS [56]												✓						



Nadi [33]	unclear	unclear	unclear	high	unclear	low	unclear	unclear
Pownall [34]	low	low	low	low	low	low	unclear	low
Ryan [35]	unclear	unclear	unclear	unclear	low	low	unclear	unclear
Schneider [36]	low							
Sentinelli [37]	unclear	unclear	unclear	unclear	unclear	low	unclear	unclear
Sreedevi [38]	low	unclear	low	low	low	low	low	low
Toobert [39]	unclear	unclear	low	low	unclear	low	low	low
White [40]	unclear	unclear	unclear	unclear	high	unclear	high	unclear
Youngwani chsetha [41]	low	low	low	low	low	low	unclear	low
Yucel [42]	unclear	unclear	unclear	unclear	low	low	unclear	unclear

Low, low risk of bias; Unclear, unable/difficult to determine risk of bias; High, high risk of bias.



	INT	+				+	+										
Ryan [35]	WL	+	+	+	+	-	-	-	-		-	+	-	+		-	-
	WL+ AE	+	+	+	+	+	-	-	-		-	-	-	-		+	+

WT, weight; BMI, body mass index; WC, waist circumference; HC, hip circumference; FM, fat mass or % body fat; LM, lean mass or muscles, kg; SBP, systolic blood pressure; DBP, diastolic blood pressure; PA, electronic physical activity monitor; TC, total cholesterol; HDL, high-density lipoprotein cholesterol; LDL, Low-density lipoprotein cholesterol; TG, triglyceride; HbA1c, glycated haemoglobin; FBG, fasting blood glucose; HOMA-IR, homeostatic model assessment insulin resistance; CGM, continuous glucose monitoring; PSS, problem solving skills; EDU, diabetes education; UC, usual care; EUC, enhanced usual care; AE, aerobic exercise; RE, resistance exercise; CE, combined exercise; SET, Supervised group exercise-therapy program; HET, Home-based exercise-therapy; PUFA, poly-unsaturated fatty acid; INT, intervention group; DB, diet beverage; WL, weight loss; PS, peer support.

+ denotes a significant post-intervention effect determined either by statistical significance ( $p < .05$ ), an effect size (Cohen's  $d$ )  $\geq 0.5$ , or a standardized mean difference (SMD)  $\geq 0.5$ ; ++ denotes a change in effect that was greater than that observed in the control/comparison group; - denotes non-significant or equivocal post-intervention effect

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